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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,216	10/12/2000	Stephen Yencho	032405-018	9923
33109	7590	12/03/2003	EXAMINER	
CARDICA, INC. 900 SAGINAW DRIVE REDWOOD CITY, CA 94063			IZAGUIRRE, ISMAEL	
			ART UNIT	PAPER NUMBER
			3765	
			DATE MAILED: 12/03/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

CS

Office Action Summary	Application No.	Applicant(s)	
	09/687,216	YENCHO ET AL.	
	Examiner	Art Unit	
	Ismael Izaguirre	3765	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>16</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

CLAIMS

Summary

Claims 1,8,14 and 23 are the independent claims under consideration in this Office Action.

Claims 2-4,7,9-13 and 15-22 are the dependent claims under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 and 7-23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Vargas et al. (6,428,550).

Vargas et al. teach a one piece anastomoses device for connecting a graft vessel to a target vessel. Vargas et al. teach the device comprising a device body 24 (see

figure 1, noted as section 24) formed of a superelastic or pseudoelastic material, such as a nickel titanium alloy (column 11, line 18), which is insertable within a graft vessel 30 and attachable to a target vessel 32. Vargas et al. teach the device as having a first insertion configuration with reduced diameter and a tissue holding configuration with a larger diameter. The body includes diamond shaped portions or struts (figure 3, for example) for expanding and conforming to the tissue holding configuration.

The body further includes an inner flange 48 (figure 4, for example) and an outer flange 50. Specifically, noting the embodiments of figures 4 and 9-11, for example, at least one of the flanges includes a radially offset flange. That is, the inner and outer flanges cooperate yet are radially offset from each other to hold the graft vessel to the target vessel (note figure 11, for example).

Vargas et al. further teach the use of barb means 74 (figure 5) for penetrating and holding the graft vessel in place on the body of the device. The body is placed in a delivery device as in figure 14 including means for holding the body in an insertion configuration. The graft vessel is placed inside the body of the device (figure 5, for example) and the graft vessel is everted for presenting the intima and penetrated by the aforementioned barbs. The body is placed within and into the intima of the target vessel and the flange is moved so as to form a hook shape in the holding configuration, as in figure 6. The other flange is then moved to clamp the graft vessel to the target vessel (figure 8, for example) by manipulating the tubular elements of the delivery device. When the vessels are coacting with each other the procedure is completed and the delivery device is withdrawn.

Claims 1,2,4 and 7-9,11-17,19,20,22 and 23 are rejected under 35 U.S.C.

§ 102(e) as being anticipated by Nobis et al. (6,605,098).

Nobis et al. teach a one piece anastomoses device for connecting a graft vessel to a target vessel. Vargas et al. teach the device comprising a device body (see figure 3c, between the leader lines of 204a and 210) formed of a medical grade material, which is insertable within a graft vessel 300 and attachable to a target vessel 902 (figure 19, for example. Nobis et al. teach the device as having a first insertion configuration with reduced diameter and a tissue holding configuration with a larger diameter. The body includes expandable portions for expanding and conforming to the tissue holding configuration.

The body further includes an inner flange 208 (figure 3c) and an outer flange 209. Specifically, at least one of the flanges includes a radially offset flange. That is, the inner and outer flanges cooperate yet are radially offset from each other to hold the graft vessel to the target vessel (note figure 19, for example). The flange 209 includes at first a non-offset portion and then has two wings that flare out offset from the flange 208 when in the tissue holding configuration.

Nobis et al. further teach the use of barb means at the end of 208 for penetrating and holding the graft vessel in place on the body of the device and on the target vessel. The body is placed in a delivery device as in figure 3c including means for holding the body in an insertion configuration. The graft vessel is placed inside the body of the device (figure 3c, for example) and the graft vessel is everted for presenting the intima and penetrated by the aforementioned barbs. The body is placed within and into the

intima of the target vessel and the flange is moved so as to form a hook shape in the holding configuration, as in figure 19. The other flange is then moved to clamp the graft vessel to the target vessel by manipulating the tubular elements of the delivery device. When the vessels are coacting with each other the procedure is completed and the delivery device is withdrawn.

Claims 1-4 and 7-23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Peterson et al. (6,599,303)

Peterson et al. teach a one piece anastomoses device for connecting a graft vessel to a target vessel. Peterson et al. teach the device comprising a device body (such as in the area of 80i of figure 23a, for example) formed of a superelastic or pseudoelastic material, such as a nickel titanium alloy (column 5, lines 33-34), which is insertable within a graft vessel 30 and attachable to a target vessel 90. Peterson et al. teach the device as having a first insertion configuration with reduced diameter and a tissue holding configuration with a larger diameter. The body includes portions or struts (figure 19a and 20a, for example) for expanding and conforming to the tissue holding configuration.

The body further includes an inner flange 86e or 86f (figures 19a and 20a, for example) and an outer flange 84e or 85f. Specifically, noting the embodiments of figures 19a, 20a, for example, at least one of the flanges includes a radially offset flange. That is, the inner and outer flanges cooperate yet are radially offset from each other to hold the graft vessel to the target vessel (note figures 19c or 20b, for example).

Peterson et al. further teach the use of barb means 89e (figure 19b) for penetrating and holding the graft vessel in place on the body of the device. The body is placed in a delivery device as in figure 8 including means for holding the body in an insertion configuration. The graft vessel is placed inside the body of the device and the graft vessel is everted (figure 23b) for presenting the intima and penetrated by the aforementioned barbs. The body is placed within and into the intima of the target vessel and the flange is moved so as to form a hook shape in the holding configuration, as in figure 20b. The other flange is then moved to clamp the graft vessel to the target vessel by manipulating the tubular elements of the delivery device as in figures 10-14, for example. When the vessels are coacting with each other the procedure is completed and the delivery device is withdrawn.

Comments

The following document is the parent document of Peterson et al. '303, noted above.

Claims 1-4 and 7-23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Peterson et al. (6,152,937)

Peterson et al. teach a one piece anastomoses device for connecting a graft vessel to a target vessel. Peterson et al. teach the device comprising a device body (such as in the area of 80 of figure 23a, for example) formed of a superelastic or pseudoelastic material, such as a nickel titanium alloy (column 5, lines 33-34), which is insertable within a graft vessel 30 and attachable to a target vessel 90. Peterson et al. teach the device as having a first insertion configuration with reduced diameter and a

tissue holding configuration with a larger diameter. The body includes portions or struts (figure 19a and 20a, for example) for expanding and conforming to the tissue holding configuration.

The body further includes an inner flange 86e or 86f (figures 19a and 20a, for example) and an outer flange 84e or 85f. Specifically, noting the embodiments of figures 19a, 20a, for example, at least one of the flanges includes a radially offset flange. That is, the inner and outer flanges cooperate yet are radially offset from each other to hold the graft vessel to the target vessel (note figures 19c or 20b, for example).

Peterson et al. further teach the use of barb means 86e (figure 19b) for penetrating and holding the graft vessel in place on the body of the device. The body is placed in a delivery device as in figure 8 including means for holding the body in an insertion configuration. The graft vessel is placed inside the body of the device and the graft vessel is everted (figure 23b) for presenting the intima and penetrated by the aforementioned barbs. The body is placed within and into the intima of the target vessel and the flange is moved so as to form a hook shape in the holding configuration, as in figure 20b. The other flange is then moved to clamp the graft vessel to the target vessel by manipulating the tubular elements of the delivery device as in figures 10-14, for example. When the vessels are coacting with each other the procedure is completed and the delivery device is withdrawn.

PERTINENT CITATIONS

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Grudan et al. and Swanson et al. illustrate devices for coupling graft vessels to target vessels and include offset flange portions.

INQUIRIES

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0861.

Any inquiry concerning this communication or earlier communications directed to the examiner should be directed to Mr. Ismael Izaguirre at (703) 308-0892 located in CP2-4B18, Monday through Friday 9:30am to 6:00pm.



**Ismael Izaguirre
Primary Examiner
Group Art Unit 3765**